

AMENDMENTS TO THE DRAWINGS

The attached "Replacement Sheets" of drawings includes changes to Figures 1-3B. The attached "Replacement Sheets," which include Figures 1-3B, replace the original sheets including Figures 1-3B.

REMARKS

Claims 1-6, 8-17, 38-40 and 52 are pending, and claims 7, 18-37, 41-51 and 53 have been cancelled without prejudice. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments contained herein.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-6, 8-9, 11-17, 38-40 and 52 stand rejected under 35 U.S.C. § 103(a) as being obvious over *Stereotaxis* (WO 00/07641) in view of *Osadchy* (U.S. Pat. No. 6,266,551). This rejection is respectfully traversed.

Independent Claim 1

Claim 1 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

The Final Office Action states on page 5 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions that take into account information on the number of magnetically responsive elements and spacing therebetween.

As the Supreme Court said, there must be an apparent reason to combine known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween that are used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Applicant submits that claim 1 is not obvious in view of *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result Of *Osadchy*'s Catheter With A Calibration Offset, And Would Not Have Been Productive Of Applicant's Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy*'s teachings might have recognized that the *Stereotaxis* system could be improved by including *Osadchy*'s stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy*'s teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Applicant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Applicant's device that stores the number of magnetically responsive elements and spacing

therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device.

The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration distance between a sensing coil and would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Applicant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 1 having stored information including a number of magnetically responsive elements.

Independent Claim 38

Claim 38 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the cross-sectional area and elastic properties of the device for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy*'s Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information on Device Elasticity/Cross-sectional Area For Use in Determining Navigation Variables

The Final Office Action states on page 9 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes geometric properties including the position of the tip 26 relative to coils 60, 62, 64, where the information is used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, ll. 26-28; c. 12, ll. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, ll. 55; c. 15, ll. 6-7). *Osadchy*'s distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, ll. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy*'s teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information including the cross-sectional area and elastic properties of the device. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the

references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007).

The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Applicant submits that claim 38 is not obvious in view of *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result Of *Osadchy's* Catheter With A Calibration Offset, And Would Not Have Been Productive Of Applicant's Device With Information On Cross-sectional Area Of The Device For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings may have recognized that the *Stereotaxis* system could be improved by including a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in

the art considering *Osadchy* would not have thought of including the cross-sectional area and elastic properties of the device that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Applicant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Applicant's device that stores the cross-sectional area and elastic properties of the device, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have combined *Osadchy's* teachings of an offset in a manner that would have predictably resulted in including the cross-sectional area and elastic properties of the device, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Applicant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 38 having stored information including a cross-sectional area and elastic properties of the device.

Independent Claim 52

Claim 52 is not obvious over the above cited references for the following reasons:

I. There is no apparent reason why an artisan considering *Osadchy's* teaching of a calibration offset would combine such teaching with *Stereotaxis* in a manner that would result in the fashion claimed, of a device that stores the number of magnetically responsive elements and spacing between for use in determining navigation variables

II. The combination of references would not have been productive of the claimed device

I. The Claimed Invention Is Not Obvious Over *Stereotaxis* And *Osadchy*, Since There Is No Apparent Reason Why An Artisan Considering *Osadchy's* Teaching Of A Calibration Offset Would Combine Such Teaching With *Stereotaxis* In A Manner That Would Result In The Fashion Claimed Of A Device With Information On The Number of Magnetic Elements For Use In Determining Navigation Variables

The Final Office Action states on page 5 that *Osadchy* discloses a device having electronic information on physical properties of the device that includes the number of magnetically responsive elements 60, 62, 64 and spacing there between (dy and dz), where the number of magnetically responsive elements and spacing are used to determine calibration correction data to enable proper determination of the tip location.

However, *Osadchy* merely discloses a distance L from a coil 62 to a tip 26, which is used for calibration, where "due to deviations in the process of manufacturing catheter 20, the distance L typically varies from one catheter to another." (*Osadchy*, c 11, II. 26-28; c. 12, II. 3-6). *Osadchy* teaches a position signal generating device 28, where "magnetic fields cause coils 60, 62 and 64 in device 28 to generate signals" and a computer uses "the position and orientation signals generated by device 28, in order to determine the actual, correct position of tip 26". (*Osadchy*, c. 10, II. 55; c. 15, II. 6-7). *Osadchy's* distance L is merely used as an offset to calibrate the determination of the actual position of the tip of a particular catheter. (*Osadchy*, c. 15, II. 17-21).

Thus, even if one skilled in the art had combined the *Stereotaxis* system with *Osadchy's* teaching of a calibration offset for determining distance between a sensing coil and the actual tip location, it would not have resulted in a system that provides actuation instructions to a navigation device that take into account information on the number of magnetically responsive elements and spacing therebetween. As the Supreme Court stated, there must be an apparent reason to combine the known elements in the references in a manner that would result in the fashion claimed by the patent application. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). The Examiner has not articulated a sufficient reason why one skilled in the art would have modified *Osadchy's* teaching of a calibration offset distance to arrive at the presently claimed invention of information including the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. Thus, the Applicant submits that claim 52 is not obvious in view of *Osadchy's* teachings.

II. The Claimed Invention Is Not Obvious In View Of *Stereotaxis* And *Osadchy*, Since An Artisan Combining *Stereotaxis* And *Osadchy* Would Merely Have Arrived At The Predictable Result of *Osadchy's* Catheter With A Calibration Offset, And Would Not Have Been Productive Of Applicant's Device With Information On The Number Of Magnetic Elements For Use In Determining Navigation Variables

A person of ordinary skill in the art considering *Osadchy's* teachings may have recognized that the *Stereotaxis* system could be improved by including a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip as in *Osadchy*. Thus, a skilled artisan would have been motivated to leave the *Stereotaxis* system as is, and to merely include *Osadchy's* teachings of a

stored calibration offset representative of the distance between a sensing coil of a catheter and the tip of the catheter.

The Federal Circuit has also stated that a reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the Appellant, or the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). Here, one skilled in the art considering *Osadchy* would not have thought of including the number of magnetic elements that could be used in determining navigational control variables for orienting the medical device, and would simply have followed the line of development flowing from *Osadchy* of including a calibration offset, and would not have been productive of the Applicant's invention.

Osadchy's teachings of a stored calibration offset representative of the distance between a sensing coil of a catheter and the catheter tip is not the same as Applicant's device that stores the number of magnetically responsive elements and spacing therebetween, which are used in determining navigational control variables for orienting/guiding the distal end of the medical device. The Supreme Court has stated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (U.S., 2007). Here, only the combination of *Stereotaxis* with *Osadchy's* known calibration representing the distance between a sensing coil and would be obvious, since it does no more than yield the predictable result of merely a medical device having a stored value representative of the distance between a sensing coil and a tip. There is no articulated reason why one skilled in the art would have

combined Osadchy's teachings of an offset in a manner that would have predictably resulted in including a number of magnetically responsive elements and the spacing therebetween, for use in determining navigational control variables for orienting/guiding the distal end of the medical device. As such, the Applicant submits that it would not have been obvious to a person of ordinary skill to combine *Osadchy's* teachings according to known methods in a manner that would have predictably resulted in a medical device as in claim 52 having stored information including a number of magnetic elements.

Claims 2-6, 8-9, 11-17 and 39-40

With regard to claims 2-6, 8-9, 11-17 and 39-40, these claims ultimately depend from claim 1, 38 or 51, which Applicants believe to be allowable in view of the above remarks. As such, the Applicants submit that claims 2-6, 8-9, 11-17 and 39-40 are also allowable for at least these reasons.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314)-726-7500.

Respectfully submitted,

Dated: MAY 13, 2008

By: Kevin Pumm
Kevin Pumm, Reg. No 49,046

Harness, Dickey & Pierce, P.L.C.
7700 Bonhomme, Suite 400
St. Louis, Missouri 63105
(314) 726-7500